

PSJ11 CVS Opp Exh 24

Leonhart Declaration

Exhibit C



U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator

Springfield, VA 22152

FEB 02 2012

IN THE MATTER OF

Holiday CVS, L.L.C.
d/b/a CVS/Pharmacy # 05195
4639 W. 1st Street
Sanford, Florida 32771

**ORDER TO SHOW CAUSE AND
IMMEDIATE SUSPENSION OF REGISTRATION**

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21,
United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Holiday CVS, L.L.C., d/b/a CVS/Pharmacy # 05195 ("CVS 05195") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration BC6988298, pursuant to 21 U.S.C. § 824(d), because such registration constitutes an imminent danger to the public health and safety. Notice is also given to afford CVS 05195 an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, or a location designated by the Administrative Law Judge, on April 10, 2012, (if CVS 05195 requests such a hearing), as to why DEA should not revoke CVS 05195's DEA Certificate of Registration BC6988298, pursuant to 21 U.S.C. § 824(a)(4), deny any pending applications for renewal or modification of such registration, and deny any applications for additional registration, pursuant to 21 U.S.C. § 823(f), because CVS 05195's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

1. CVS 05195 is registered with DEA as a chain pharmacy in Schedules II-V under DEA registration number BC6988298 at 4639 W. 1st Street, Sanford, Florida 32771. DEA Certificate of Registration BC6988298 will expire by its terms on December 31, 2013.
2. From January 1, 2008 through December 31, 2011, Automation of Reports and Consolidated Orders System ("ARCOS") data shows that CVS 05195 purchased over 2.2 million dosage units of oxycodone from its distributor, Cardinal Health.
3. From 2008 to 2009, CVS 05195 increased the amount of oxycodone it purchased by 56%, from 66,900 dosage units of oxycodone in 2008 to 104,500 dosage units of oxycodone

in 2009. In 2010, CVS 05195 purchased 885,900 dosage units of oxycodone, a 748% increase over 2009. In 2011, CVS 05195 purchased over 1.2 million dosage units of oxycodone. The enormous quantities of oxycodone purchased by CVS 05195 considerably surpassed the amount of oxycodone ordinarily purchased by a retail pharmacy.

4. Since at least 2010, CVS 05195 has dispensed controlled substances to customers under circumstances indicating that the drugs are diverted from legitimate channels, misused or abused. These include, but are not limited to, the following circumstances:

- a. DEA and the State of Florida have taken criminal, civil or administrative action against at least 20 physicians, whose customers fill their controlled substance prescriptions at CVS 05195, for activities resulting in the diversion of controlled substances, including for inappropriately prescribing excessive and inappropriate quantities of controlled substances and issuing prescriptions not for a legitimate medical purpose or outside the usual course of professional practice. These actions resulted in the loss of authority of these practitioners to handle controlled substances. Many of these practitioners subsequently voluntarily surrendered their DEA registrations for cause, based on their failure to comply with the Controlled Substances Act and DEA regulations.
 - b. CVS 05195 Pharmacist in Charge, Jessica Merrill, admitted to DEA investigators that CVS 05195 dispensed controlled substances where the pharmacy knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose, including circumstances where the pharmacy knew or should have known that the controlled substances were abused and/or diverted by the customer. The Pharmacist in Charge further stated that she set daily limits of how many oxycodone prescriptions CVS 05195 would fill each day to ensure that she had enough oxycodone for the “real pain patients.”
5. Despite the specific guidance provided to CVS Caremark Corporation by DEA and despite the public information readily available regarding the oxycodone epidemic in Florida, CVS 05195 nonetheless failed in carrying out its responsibilities as a DEA registrant. Based on the facts as outlined above, CVS 05195 failed to exercise its corresponding responsibility regarding the proper prescribing and dispensing of controlled substances in violation of 21 C.F.R. § 1306.04(a), and CVS 05195 failed to maintain effective controls against diversion of controlled substances in violation of 21 C.F.R. § 1301.76. CVS 05195 knew, or should have known, that a large number of the prescriptions for controlled substances that it filled were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice.

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4), it is my preliminary finding that CVS 05195's continued registration is inconsistent with the public interest. Under the facts and circumstances described herein, it is my conclusion that CVS 05195's continued registration while these proceedings are pending constitutes an imminent danger to the public health and safety. *See* 21 U.S.C. § 824(d). Accordingly, pursuant to the

provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration BC6988298 is hereby suspended, effective immediately. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that CVS 05195 possess pursuant to the registration which I have herein suspended. The said Agents and Investigators are also directed to take into their possession CVS 05195's DEA Certificate of Registration BC6988298 and any unused order forms.

THE following procedures are available to you in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, CVS 05195 may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If CVS 05195 fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, CVS 05195 may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).
3. Should CVS 05195 decline to file a request for a hearing or, should CVS 05195 request a hearing and then fail to appear at the designated hearing, CVS 05195 shall be deemed to have waived the right to a hearing and the DEA may cancel such hearing, and I may enter my final order in this matter without a hearing based upon the evidence presented to me. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrisette Drive, Springfield, VA 22152.


Michele M. Leonhart
Administrator
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Christine M. Menendez, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters
Office of the Administrative Law Judges
Hearing Clerk
8701 Morrisette Drive
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]
- (B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]
- (C) [State briefly the position of the person with regard to the particular objections or issues.]
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant
or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

Leonhart Declaration

Exhibit D



U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator

Springfield, VA 22152

FEB 02 2012

IN THE MATTER OF

Holiday CVS, L.L.C.
d/b/a CVS/Pharmacy # 00219
3798 Orlando Drive
Sanford, Florida 32773

**ORDER TO SHOW CAUSE AND
IMMEDIATE SUSPENSION OF REGISTRATION**

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21,
United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Holiday CVS, L.L.C., d/b/a CVS/Pharmacy # 00219 ("CVS 00219") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration BC5289055, pursuant to 21 U.S.C. § 824(d), because such registration constitutes an imminent danger to the public health and safety. Notice is also given to afford CVS 00219 an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, or a location designated by the Administrative Law Judge, on April 3, 2012, (if CVS 00219 requests such a hearing), as to why DEA should not revoke CVS 00219's DEA Certificate of Registration BC5289055, pursuant to 21 U.S.C. § 824(a)(4), deny any pending applications for renewal or modification of such registration, and deny any applications for additional registration, pursuant to 21 U.S.C. § 823(f), because CVS 00219's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

1. CVS 00219 is registered with DEA as a chain pharmacy in Schedules II-V under DEA registration number BC5289055 at 3798 Orlando Drive, Sanford, Florida 32773. DEA Certificate of Registration BC5289055 will expire by its terms on December 31, 2013.
2. From January 1, 2008 through December 31, 2011, Automation of Reports and Consolidated Orders System ("ARCOS") data shows that CVS 00219 purchased over 5.8 million dosage units of oxycodone from its distributors, primarily from Cardinal Health.

3. From 2008 to 2009, CVS 00219 increased the amount of oxycodone it purchased by approximately 75%, from 719,400 dosage units of oxycodone in 2008 to 1.25 million dosage units of oxycodone in 2009. In 2010, CVS 00219 purchased over 2 million dosage units of oxycodone, an approximately 62% increase over 2009. In 2011, CVS 00219 purchased over 1.8 million dosage units of oxycodone. The enormous quantities of oxycodone purchased by CVS 00219 considerably surpassed the amount of oxycodone ordinarily purchased by a retail pharmacy.

4. Since at least 2010, CVS 00219 has dispensed controlled substances to customers under circumstances indicating that the drugs are diverted from legitimate channels, misused or abused. These include, but are not limited to, the following circumstances:

- a. DEA and the State of Florida have taken criminal, civil or administrative action against at least 20 physicians, whose customers fill their controlled substance prescriptions at CVS 00219, for activities resulting in the diversion of controlled substances, including for inappropriately prescribing excessive and inappropriate quantities of controlled substances and issuing prescriptions not for a legitimate medical purpose or outside the usual course of professional practice. These actions resulted in the loss of authority of these practitioners to handle controlled substances. Many of these practitioners subsequently voluntarily surrendered their DEA registrations for cause, based on their failure to comply with the Controlled Substances Act and DEA regulations.
 - b. CVS 00219 Pharmacist in Charge, Paras Priyadarshi, admitted to DEA investigators that CVS 00219 dispensed controlled substances where the pharmacy knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose, including circumstances where the pharmacy knew or should have known that the controlled substances were abused and/or diverted by the customer.
5. Despite the specific guidance provided to CVS Caremark Corporation by DEA and despite the public information readily available regarding the oxycodone epidemic in Florida, CVS 00219 nonetheless failed in carrying out its responsibilities as a DEA registrant. Based on the facts as outlined above, CVS 00219 has failed to exercise its corresponding responsibility regarding the proper prescribing and dispensing of controlled substances in violation of 21 C.F.R. § 1306.04(a), and CVS 00219 has failed to maintain effective controls against diversion of controlled substances in violation of 21 C.F.R. § 1301.76. CVS 00219 knew, or should have known, that a large number of the prescriptions for controlled substances that it filled were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice.

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4), it is my preliminary finding that CVS 00219's continued registration is inconsistent with the public interest. Under the facts and circumstances described herein, it is my conclusion that CVS 00219's continued registration while these proceedings are pending constitutes an imminent danger to the public health and safety. *See* 21 U.S.C. § 824(d). Accordingly, pursuant to the

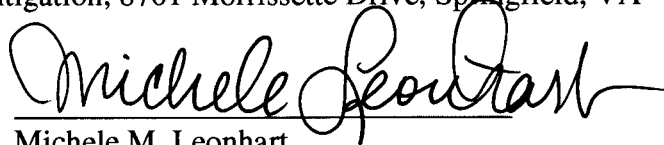
provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration BC5289055 is hereby suspended, effective immediately. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that CVS 00219 possess pursuant to the registration which I have herein suspended. The said Agents and Investigators are also directed to take into their possession CVS 00219's DEA Certificate of Registration BC5289055 and any unused order forms.

THE following procedures are available to you in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, CVS 00219 may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If CVS 00219 fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, CVS 00219 may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).
3. Should CVS 00219 decline to file a request for a hearing or, should CVS 00219 request a hearing and then fail to appear at the designated hearing, CVS 00219 shall be deemed to have waived the right to a hearing and the DEA may cancel such hearing, and I may enter my final order in this matter without a hearing based upon the evidence presented to me. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrisette Drive, Springfield, VA 22152.



Michele M. Leonhart
Administrator
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Christine M. Menendez, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters
Office of the Administrative Law Judges
Hearing Clerk
8701 Morrisette Drive
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]
- (B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]
- (C) [State briefly the position of the person with regard to the particular objections or issues.]
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant
or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.